

Congress of the United States
Washington, DC 20515

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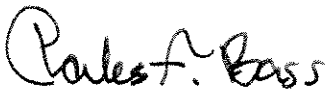
**Experts Say Current Stem Cell Research Policy
Impedes Scientific Progress**

Dear Colleague,


Last week, a number of NIH Institute Directors publicly stated that the current federal embryonic stem cell policy is overly restrictive and is hindering scientific progress. These top experts expressed serious concerns with current policy. We would like to share a relevant article from *Science Magazine* with you (attached).

The current embryonic stem cell policy must be changed. We can no longer tie the hands of our scientists when millions of lives are at stake. We hope you will join us in cosponsoring H.R. 810, the Castle-DeGette "Stem Cell Research Enhancement Act." This bill provides for an expanded embryonic stem cell research policy and requires that strong ethical standards be implemented. For more information, contact Amy Judge with Congressman Langevin at (202) 225-5976 or Alissa Southworth with Congressman Bass at (202) 225-5206.

Sincerely,



Charles Bass
Member of Congress



James R. Langevin
Member of Congress

STEM CELLS

Restiveness Grows at NIH Over Bush Research Restrictions

Dissatisfaction within the National Institutes of Health (NIH) is growing over the Bush Administration's restrictions on funding for

work with human embryonic stem (ES) cells. Meanwhile, measures to loosen restrictions may finally make it to the floor this year in Congress.

At a hearing last week by a Senate appropriations subcommittee chaired by Arlen Specter (R-PA), NIH Director

Elias Zerhouni seemed to defend the policy only reluctantly, citing "mounting evidence" that as the 22 approved cell lines age, an increasing number of problems are arising because of genetic instability. "Clearly, from a scientific standpoint, more might be helpful," said Zerhouni, who pointed out that

the Bush policy forbidding the use of cell lines derived after 9 August 2001 is based on moral and ethical concerns. Asked by Specter "where is the moral issue" for embryos that are slated for disposal anyway, Zerhouni responded, "I think you'll have to ask that from those who hold that view."

Specter also released letters from several institute directors chafing at restrictions and warning that NIH could be falling behind in the field. Specter got some unvarnished sentiment by telling the directors to answer a set of

questions he posed "without editing, revision, or comment by the Department of Health and Human Services." The following are some excerpts:

• Elizabeth G. Nabel, director of the National Heart, Lung, and Blood Institute: "NIH has ceded leadership in this field to the new California agency. ... Because U.S. researchers who depend on Federal funds lack access to newer hESC lines, they are at a tech-

nological disadvantage. ... The restricted access will hamper NIH's ability to recruit ... young scientists."

• James Battey, director of the National Institute on Deafness and Other Communication Disorders (and until last month chair of the NIH Stem Cell Task Force): "The science is evolving very rapidly, and limitations of the President's policy [have] become more apparent since I last testified. ... It is likely that there will be a movement of some of the best stem cell biologists to California."

• Duane Alexander, director of the National Institute of Child Health and Human Development: "NICHD scientists report some problems in obtaining ... cell lines, [including] inadequate quantity and quality, ... high prices, 'cumbersome' procedures, and long waiting times."

"NIH has ceded leadership in this field to the new California agency."

Elizabeth G. Nabel

—Elizabeth G. Nabel
Director, NHLBI

Battey—who said last week that the new conflict-of-interest rules that forbid many NIH managers and their families from owning stock in biomedical companies are compelling

him to leave NIH—agrees that frustration over stem cell research constraints has been growing steadily at the agency. "I think many of our finest scientists are troubled by the policy," he told *Science*. He points out that ▶

AIDS RESEARCH

IOM Panel Clears HIV Prevention Study

An Institute of Medicine (IOM) panel has found no major improprieties in the conduct of a key HIV trial in Uganda to prevent mother-to-child transmission in the late 1990s, essentially validating the use of a cheap, effective, and simple anti-HIV drug: nevirapine. The report also helps clear the names of Johns Hopkins University pathologist Brooks Jackson and more than a dozen colleagues.

In two papers published in *The Lancet* in 1999 and 2003, National Institutes of Health (NIH)-funded researchers reported that giving a pregnant woman a single dose of nevirapine, and her infant a single dose immediately after birth, dramatically cut mother-to-child transmission rates. Since then, nevirapine has become the cornerstone of HIV prevention efforts in infants across Africa and beyond. But last year the work came under fire from an NIH staffer, Jonathan Fishbein, who

charged that the investigators failed to adhere to regulatory standards governing data collection and record keeping (*Science*, 24 December 2004, p. 2168). He argued in an interview that "you cannot use this trial as part of the knowledge about how that drug works."

The nine-member IOM committee agreed that the study wasn't foolproof. But "we feel firmly that the findings and the conclusion ... are valid," said committee member Mark Kline, a pediatric infectious disease specialist at Baylor College of Medicine in Houston, Texas. The committee had primary medical records sent from Uganda and focused on a sampling of 49 infants in the study. About 10% of adverse events went unreported in that sample, they noted.

Fishbein immediately blasted the IOM report as "an apologist's statement" that supported NIH's point of view. At a tense

press conference, he and his brother, Rand Fishbein, a defense and foreign policy consultant, asked how the IOM committee could be unbiased, given that six of its members receive NIH grants.

IOM president Harvey Fineberg called that accusation "preposterous," adding that "there is nothing financially at stake for the individuals on this committee."

Some in the AIDS prevention field, who have worried that African governments would abandon nevirapine, are hoping that the IOM report will end the controversy. The Ugandan trial "was a critical pilot study" of nevirapine that has been confirmed by at least a half-dozen others, says Arthur Ammann, a pediatric immunologist and president of Global Strategies for HIV Prevention in San Francisco.

—JENNIFER COUZIN

CREDIT: RICK KOZAK

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newer cell lines are being grown free of contamination from animal products, and that one of scientists' goals—creating ES cell lines that can be used as models to study diseases—is being fulfilled at the Reproductive Genetics Institute in Chicago, Illinois. That fertility clinic claims it has created 50 cell lines representing six genetic diseases, including muscular dystrophy, from fertilized eggs that otherwise would have been discarded. But none of them can be touched by a U.S. government-funded researcher.

Batthey is most worried about the effect of the federal restrictions on young scientists. "Young people are now electing to stay

"Limitations of the President's policy [have] become more apparent since I last testified in April 2004."

—James F. Batthey Jr.
Director, NIDCD

away" from research with human ES cells, he says. Mahendra Rao, who does stem cell research at the National Institute on Aging, says he's experiencing that firsthand: "I have four postdoc positions vacant in my

lab." He says he knows of at least three colleagues—not counting Batthey and Arlene Chiu (who just accepted a job in California; see p. 351)—who have interviewed for jobs in California.

The White House continues to stand firm against any revision in the policy, but pressure continues to grow in Congress. Last month, the moderate Republican sponsor of a bill to expand stem cell availability, Michael Castle (DE), got House Speaker Dennis Hastert (R-IL) to agree to schedule a vote on it this year.

—CONSTANCE HOLDEN

With reporting by Jocelyn Kaiser.

NUCLEAR WASTE

Academy Gets the Word Out After Tussle With Agency

The National Academies (NAS) released a report last week that says dry storage of aging spent nuclear fuel offers "inherent security advantages" over submerging the rods in pools at reactor sites. The fact that a sponsor, the Nuclear Regulatory Commission (NRC), disagrees with that message is not unusual. What makes this report stand out is that the two sides spent 8 months negotiating a public version, and that the NRC preempted the academy by going public with a point-by-point rebuttal of the document while it was still under wraps. The episode is the latest illustration of ongoing problems between NAS and the government over handling of sensitive but unclassified data (*Science*, 22 November 2002, p. 1548).

With no active repository for radioactive materials, some 54,000 tons of nuclear fuel have accumulated at U.S. reactors since the 1970s. Most of the fuel sits in pools, raising the concern that a terrorist attack could drain the water from the pools, causing the fuel to ignite and emit radioactive material over a large area. Congress called for the study after a 2003 paper said pools posed a safety threat "worse than ... Chernobyl," a conclusion the NRC said lacked a "sound technical basis."

Last July the academy panel sent Congress a classified version of its report that raised concerns about the pools and urged NRC to take a fresh look at the problem. Separate dry casks, it said, are more robust than pools and would allow plants to disperse the older fuel. It also suggested redistributing hot fuels and installing water-cooling systems to cope with leaks. Daniel Dorman, NRC

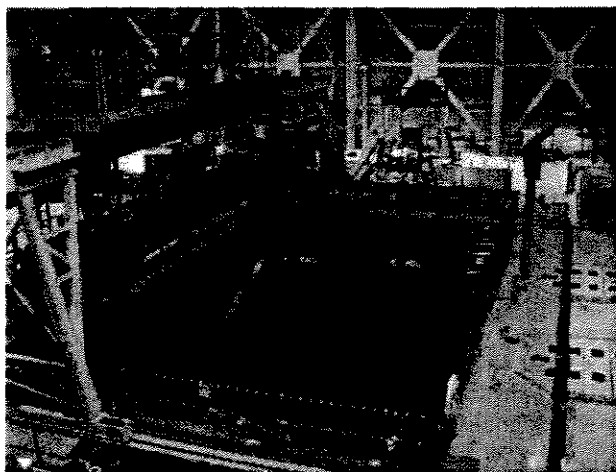
deputy director for nuclear security, says that pools and dry storage "both provide adequate protection" and that new steps to protect spent fuel are under way. At the same time, he says NRC agrees with the report's call for more outside review of the issue and its assertion that any theft of rods to make dirty bombs is unlikely.

The academy panel then turned to producing a public version. Getting the word out, however, proved arduous. In December, NRC rejected a draft version despite the fact that NAS left out data on how fuel rod fires could overheat, potential radiation releases, and specific attack scenarios. That material had been withheld as a precaution, according to panel members, but NRC told the academy that the draft was still "permeated with sensitive information" and requested an entirely new version. "That's not the way we operate," says committee director Kevin Crowley, who asked NRC for specific security concerns.

In March, before the parties could agree on a public version, NRC released a point-by-point response to much of the classified report. The academy, officials wrote, was asking for "more than what was needed." Last week NRC officials admitted that the document overstated a finding of the academy report by claiming that the committee had

called for "earlier movement of spent fuel from pools into dry storage" when it had not.

After the dustup hit the papers, legislators demanded a public version. Last week it appeared, in a version that panelists and academy officials say is substantially unchanged from the November draft. This week, NRC



Hot rods. Academy report points to security flaws in keeping spent nuclear fuel in pools long after it has cooled.

said the public report "alleviated [its] concerns about sensitive information."

"The academy clearly doesn't want to provide information that could be damaging to the country," says NAS Executive Officer E. William Colglazier. But without clearer rules governing what should be secret, he adds, "I wouldn't say we're not going to have this problem again."

—ELI KINTISCH

CREDIT: NRC